



Title 10
MARYLAND DEPARTMENT OF HEALTH
Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS
COMMISSION

10.62.01 Definitions

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(13) (text unchanged)

(14) *Edible Cannabis Product.*

(a) *“Edible cannabis product” means a medical cannabis product intended for human consumption by oral ingestion, in whole or in part.*

(b) *“Edible cannabis product” includes medical cannabis products that dissolve or disintegrate in the mouth.*

(c) *“Edible cannabis product” does not include any:*

(i) *Medical cannabis concentrate;*

(ii) *Medical cannabis-infused product, including an oil, a wax, an ointment, a salve, a tincture, a capsule, a suppository, a dermal patch, or a cartridge; or*

(iii) *Other dosage form that is recognized by the United States Pharmacopeia, the National Formulary, or the Food and Drug Administration and is approved by the Commission.*

[(14)] (15) (text unchanged)

(16) *“Green waste” means unauthorized, misbranded, contaminated, unused, surplus, returned, or out-of-date medical cannabis or any product containing medical cannabis.*

[(15)] (17) (text unchanged)

(18) “Inspector” means any member of the Commission or any State employee or contractor designated by the Commission to carry out an inspection under this subtitle.

[(16)] (19)—[(21)] (25) (text unchanged)

[(23)] (26) “Medical cannabis concentrate” means a product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of:

- (a) Solvents;
- (b) Carbon dioxide; or
- (c) Heat, screens, presses or steam distillation.

[(24)] (27) “Medical cannabis finished product” means any usable cannabis, medical cannabis concentrate, *edible cannabis product*, product containing a medical cannabis concentrate, or [a] *any other type of medical cannabis-infused product intended to be packaged and labeled for release to a qualifying patient without further processing.*

[(25)] (28) Medical Cannabis-Infused Product.

(a) “Medical cannabis-infused product” means oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that dried leaves and flowers are integrated into other material.

(b) “Medical cannabis-infused product” does not include [a food] *an edible cannabis product* as that term is defined in [Health-General Article, §21-101, Annotated Code of Maryland] *COMAR 10.62.01.01B(14)*.

[(26)] (29) —[(40)] (43) (text unchanged)

10.62.17 Complaints, Adverse Events, and Recall

.02 Report of Serious Adverse Event to Commission and Interested Parties.

In the event a complaint associated with a serious adverse event is received, a licensee, or certifying provider, shall [promptly] *within 24 hours* report the complaint to:

- A. The Commission;
- B. [Either the] *The* licensed grower from which the medical cannabis originated[, or] *and, if applicable,* the licensed processor from which the medical cannabis [concentrate] *finished product* originated; and

C. The certifying provider caring for the qualifying patient.

.03 Complaint Investigation by Grower or Dispensary.

A. Whenever a complaint regarding the quality or safety of medical cannabis is received by a licensed grower, licensed processor or licensed dispensary, a licensee shall, within 24 hours[, review the complaint to determine if it is substantive or reports a serious adverse event.

B. If a licensee determines that the complaint is substantive or reports a serious adverse event, a licensee shall]:

(1) Report the complaint to the Commission in order for the Commission to determine if the complaint is substantive or a serious adverse event;

[(1)] (2) Promptly determine the batch number or lot number of the medical cannabis, the medical cannabis [finished] -*infused* product, [and] medical cannabis concentrate, *or edible cannabis product, or any other products that are* the subject of the complaint; and

[(2)] (3) Investigate the record and circumstances of the production of the batch or lot to determine:

(a) If there was a deviation from the standard operating procedure in the production of the [medical cannabis] *batch or lot* by reviewing production logs; [and]

(b) If the sample meets quality and safety standards by submitting parts of the retention samples of the batch or lot to an independent testing laboratory[.]; *and*

(c) If there is reasonable cause to suspect communicable disease transmission, collect morbidity history from any suspected agents.

C. If sample analysis of the batch or lot reveals that the batch or lot fails to meet quality and safety standards, the licensee shall:

(1) Order a recall of all products derived from or included in the batch or lot;

(2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis from such a batch or lot of the recall; and

(3) [Offer and pay] *Pay* reimbursement for any returned medical cannabis.

D. In [a] *the* case of a report of a serious adverse event or a substantive complaint, if the investigation reveals a deviation from the standard operating procedure in the production of the batch or lot, the licensee [may] *shall*:

(1) Order a recall of all products derived from or included in the batch or lot;

(2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis [products] from such a batch or lot of the recall; and

(3) [Offer and pay] *Pay* reimbursement for any returned medical cannabis.

E. In the case of a report of a serious adverse event or substantive complaint, if the licensee's investigation reveals there is reasonable cause to suspect communicable disease transmission from an agent, the licensee shall ensure that appropriate follow-up action is taken, whenever applicable, including:

(1) Immediate exclusion of any indicated agents from all positions within the licensed premises;

(2) An order to recall all products derived from, or included in, any affected batch or lot;

(3) Notification to all patients, caregivers, and dispensaries who may have obtained medical cannabis from any affected batch or lot of the recall;

(4) Reimbursement for any returned medical cannabis;

(5) Immediate closure of the licensed premises until medical and epidemiological evidence shows that the likelihood of further disease transmission is low; and

(6) An investigation, a report, and the control of a communicable disease outbreak that is conducted in accordance with the provisions of COMAR 10.06.01.

10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

(3) "Tincture" means a cannabis-infused solution derived either directly from the cannabis plant or from a processed cannabis extract *that is* [typically] combined with 50% or greater food grade ethyl alcohol, glycerin, or vegetable oils *that*:

(a) Are distributed in a dropper bottle of four ounces or less;

(b) Contain no additional non-cannabis ingredients except potable water, unless approved by the Commission; and

(c) For vegetable oil tinctures, are manufactured in accordance with the

regulation of edible cannabis products under COMAR 10.62.37, except for COMAR 10.62.37.03 and COMAR 10.62.37.12B.

10.62.24 Medical Cannabis Finished Products Packaging

.01 Packaging of Medical Cannabis Finished Products.

A. (text unchanged)

B. Packaging Requirements. A package of a medical cannabis finished product shall:

(1)—(4) (text unchanged)

(5) Bear a clear warning that:

(a) (text unchanged)

(b) It is illegal for any person to possess or consume the contents of the package other than the qualifying patient; [and]

(c) (text unchanged)

(d) *“Consumption of medical cannabis may impair your ability to drive a car or operate machinery. Please use extreme caution.”*;

(e) *“There may be health risks associated with cannabis use, especially during pregnancy or breastfeeding.”*; and

(f) *“This package contains cannabis. Keep out of the reach of children and animals.”*;

[(6) Bear a clear warning to keep the package and its contents away from children other than a qualifying patient;]

(6) *Display the following symbol or easily recognizable mark issued by the Commission that indicates that the package contains medical cannabis:*

[Insert Universal Symbol]

[(7)] (6)—[(12)] (11) (text unchanged)

C. (text unchanged)

10.62.29 Licensed Dispensary Packaging and Labeling for Distribution

.01 Packaging Medical Cannabis for Distribution to a Qualifying Patient or Caregiver.

A. (text unchanged)

B. Packaging Requirements. A package of medical cannabis for distribution to a qualifying patient or caregiver shall:

(1)—(5) (text unchanged)

(6) Bear a clear warning that:

(a) (text unchanged)

(b) It is illegal for any person to possess or consume the contents of the package other than the qualifying patient; [and]

(c) (text unchanged)

(d) *“Consumption of medical cannabis may impair your ability to drive a car or operate machinery. Please use extreme caution.”*;

(e) *“There may be health risks associated with cannabis use, especially during pregnancy or breast-feeding.”*; and

(f) *“This package contains cannabis. Keep out of the reach of children and animals.”*;

[(7) Bear a clear warning to keep the package and its contents away from children;]

(7) *Display the following symbol or easily recognizable mark issued by the Commission that indicates the package contains medical cannabis:*

[Insert Universal Symbol]

(8)—(13) (text unchanged)

C.—F. (text unchanged)

10.62.35 Fee Schedule

.01 Fees.

The following fees are established by the Commission:

A.—J. (text unchanged)

K. Edible Cannabis Product Permit Fees:

(1) *Application fee – \$1,000; and*

(2) *Annual permit fee – \$1,000.*

[K.] *L. (text unchanged)*

10.62.37 Edible Cannabis Products

.01 Definitions.

A. *In this chapter, the following terms have the meanings indicated.*

B. *Terms Defined.*

(1) *“Approving Authority” means the agency designated in the laws of Maryland, another state, or another country to license or permit a food processing plant.*

(2) *“Approved source” means:*

(a) *A source of medical cannabis approved, licensed, and regulated by the Commission; or*

(b) *A source of food ingredients that is regulated by an approving authority.*

(3) *“Commercially sterile” means the condition achieved by the:*

(a) *Application of heat, pressure, or other energy or matter that renders a food ingredient free of:*

(i) *Microorganisms capable of reproducing in the food ingredient under normal non-refrigerated conditions of storage and distribution; and*

(ii) *Viable microorganisms, including spores, that cause disease; or*

(b) *Control of water activity and the application of heat, pressure, or other energy or matter that renders the food ingredient free of microorganisms capable of reproducing in the food ingredient under normal non-refrigerated conditions of storage and distribution.*

(4) *“Cookware” means items used during the processing of ingredients or edible cannabis products, including pots, pans, utensils, and containers.*

(5) *“Critical control point” means a point in the receiving, storage, processing, or distribution of ingredients or edible cannabis products where there is a reasonable likelihood that improper control may cause, allow, or contribute to a hazard to public health.*

(6) *Critical Item.*

(a) *"Critical item" means a safety requirement that if violated requires:*

- (i) *Immediate correction;*
- (ii) *Destruction of any ingredients or edible cannabis products which may be affected;*
- (iii) *The cessation of some or all processing operations; or*
- (iv) *Closure of the licensed premises.*

(b) *"Critical item" includes the following requirements:*

- (i) *Food ingredients shall be obtained from an approved source and approved for human consumption by an approving authority;*
- (ii) *Cannabis ingredients shall be obtained from an approved source;*
- (iii) *All ingredients and edible cannabis products shall be protected from contamination;*
- (iv) *All processes shall provide safe edible cannabis products with proper control at critical control points;*
- (v) *Licensed processor sanitation shall be adequate, provide safety, and prevent illness transmissible through edible cannabis products or ingredients;*
- (vi) *Equipment must allow for proper processing and sanitation;*
- (vii) *Edible cannabis products shall be packaged and labeled for safety;*
- (viii) *A sufficient volume of potable hot and cold water supply under adequate pressure shall be available to facilitate proper handwashing procedures outlined in this chapter; and*
- (ix) *Sewage shall be discharged in compliance with applicable laws and regulations.*

(7) *"Food" means any substance that is used as food or drink for human beings or as a component of food or drink for human beings*

(8) *“Food ingredient” means a substance that is used as a component of food, including:*

(a) Flavoring;

(b) Food coloring; and

(c) Preservatives.

(9) *“Ingredient” means any component of an edible cannabis product that is intended for human consumption, approved by the Commission, and comprised of:*

(a) Food or food ingredients; or

(b) Medical cannabis.

(10) *“Permit” means a permit issued by the Commission to a licensed processor for the purpose of manufacturing edible cannabis products.*

(11) *“Permittee” means a licensed processor authorized by the Commission to manufacture edible cannabis products.*

(12) *Potentially-Hazardous Edible Cannabis Product.*

(a) “Potentially-hazardous edible cannabis product” means an edible cannabis product that requires temperature control because the product is in a form capable of supporting:

(i) The rapid and progressive growth of infectious or toxigenic microorganisms; or

(ii) The growth and toxin production of Clostridium botulinum.

(b) “Potentially-hazardous edible cannabis product” does not include products with a water activity (aw) value of 0.85 or less.

(13) *Potentially-Hazardous Ingredient.*

(a) “Potentially-hazardous ingredient” means a natural or synthetic component of food or an edible cannabis product intended for human consumption that requires temperature control because the ingredient is in a form capable of supporting:

(i) The rapid and progressive growth of infectious or toxigenic

microorganisms; or

(ii) The growth and toxin production of Clostridium botulinum;

(b) "Potentially-hazardous ingredient" does not include an ingredient with a:

(i) Water activity (aw) value of 0.85 or less;

(ii) pH level of 4.6 or below when measured at 75°F; or

(iii) Commercially sterile ingredient in a hermetically sealed container.

(14) "Quarantine area" means an area within a licensed premises in which ingredients, medical cannabis, or medical cannabis finished products that may be contaminated are temporarily stored prior to disposal or collection by a public health agency.

.02 Categorization as Edible Cannabis Products

Food or a food ingredient that is mixed, infused, or comes into contact with medical cannabis is considered and regulated as an edible cannabis product under this chapter.

.03 Issuance of Permit.

A. Before engaging in the business of possessing, processing, packaging, labeling, transferring, transporting, selling, or distributing to a dispensary edible cannabis products, a licensed processor shall obtain a permit from the Commission.

(1) To obtain a permit, a licensed processor shall:

(a) Submit a completed permit application;

(b) Pay the registration fee specified in COMAR 10.62.35;

(c) Establish and follow written standard operating procedures and scheduled processes in accordance with §B(2) of this regulation;

(d) Pass a pre-operation inspection; and

(e) Conspicuously post applicable State and local licenses in the licensed premises.

B. The licensed processor may apply for a permit to manufacture edible cannabis products at:

(1) The licensed processor's premises; or

(2) A facility under the legal control of the licensed processor that meets:

(a) All zoning and planning requirements; and

(b) The requirements of this chapter.

C. The Commission may deny a permit if the licensed processor:

(1) Violates or fails to meet the requirements of this chapter; or

(2) Fraudulently or deceptively attempts to obtain a permit.

.04 General Premises Requirements.

A. The premises and operations shall conform to all local zoning and planning requirements.

B. A permit to process edible cannabis products shall be conspicuously displayed in the premises.

C. No major renovation or modification to the premises may be undertaken unless the Commission:

(1) Has received notice in the form prescribed by the Commission; and

(2) Issues written approval for the renovation or modification.

D. The premises shall be completely separated from an area used as living quarters by solid, impervious floors, walls, and ceilings with no connecting openings.

E. A room or area in which ingredients or edible cannabis products are processed or stored, or in which cookware or equipment are cleaned, sanitized, or stored shall:

(1) Be separated from other rooms or areas in the licensed premises by tight walls, ceilings, and self-closing doors;

(2) Be refrigerated or mechanically ventilated using exhaust and supply fans to:

(a) Remove grease vapors, steam, condensation, heat, and odor;

(1) A room or area in which ingredients or edible cannabis products are processed or stored, or in which cookware or equipment are cleaned, sanitized, or stored, shall have artificial lights that provide at a minimum:

(a) 40-foot candles of light on all work surfaces used for processing and warewashing; and

(b) 20-foot candles of light on surfaces used solely for storage.

(2) The artificial lighting shall consist of:

(a) Shatter-resistant bulbs; or

(b) Light shields that protect exposed light bulbs or fixtures from breakage and prevent glass fragments from contacting ingredients, edible cannabis products, or contact surfaces.

H. Floor drains.

(1) The permittee shall:

(a) If a floor receives water as a result of processing or cleaning, install and maintain floor drains at a rate of one floor drain for every 400 square feet of floor area; and

(b) Ensure that the floor is sloped to one or more floor drains at a pitch of 1/8 to 1/4 inch per foot.

(2) Pooling or standing water is not allowed.

I. Lavatories.

(1) The premises shall be constructed to include:

(a) A separate, gender-segregated lavatory for men and women, or a gender neutral lavatory; and

(b) One toilet for the following number of agents who are on duty at the same time:

(i) Every 15 agents; and

(ii) Any fraction of 15 agents.

(2) A lavatory may not open directly into an area in which:

(a) Ingredients or edible cannabis products are stored, processed, packaged, or labeled; or

(b) Cookware or equipment is washed or stored.

(3) Each lavatory shall be equipped with:

(a) Ventilation with mechanical air exhaust at the rate of 2 cubic feet per minute of air for each square foot of floor area or a screened window that allows the entrance of outside air;

(b) Easily cleanable and durable walls and ceiling;

(c) A smooth, impervious, and easily cleanable floor;

(d) Artificial lighting that provides 20-foot candles of light when measured 30 inches above the floor;

(e) A handwashing sink;

(f) Soap;

(g) Paper towels or warm air hand drying devices;

(h) Warm water of sufficient volume under pressure for effective hand washing according to the procedures set forth in this chapter; and

(i) A covered trash receptacle.

J. Non-Green Waste.

(1) The premises shall include non-green waste containers that are:

(a) Adequate in number to maintain sanitary conditions;

(b) Accessible to agents at locations where non-green waste is generated;

(c) Labeled as not suitable for any green waste;

(d) Easily cleanable; and

(e) Placed on a hard and impermeable surface.

(2) Non-green waste containers located inside shall be leak proof, and emptied and cleaned at least daily.

(3) Non-green waste containers located outdoors shall be:

(a) Leak-, vermin-, and insect-proof;

(b) Provided with a drain that conveys wastewater from the container directly into a sewerage system that meets all applicable State and local codes and properly disposes of the wastewater;

(c) Large enough to hold waste until the waste is taken off-site; and

(d) Covered.

K. In any event where the permittee is unable to ensure adequate sanitation, such as during an electrical outage or water shut-off, the permittee shall:

(a) Cease all edible cannabis processing;

(b) Conduct a risk analysis to determine whether any ingredients, edible cannabis products, packaging or labeling materials were contaminated; and

(c) Notify the Commission within 24 hours of the event.

.05 Receipt of Ingredients.

A. Ingredients and other supplies necessary to process edible cannabis products must be received in a designated area identified in the standard operating procedures.

B. This regulation does not apply to the receipt of medical cannabis, medical cannabis concentrates, or medical cannabis-infused products that are not intended to be used as an ingredient in edible cannabis products.

C. Each receiving area must have a barrier that reasonably prevents the entry of:

(1) Insects;

(2) Vermin;

(3) Pathogenic microorganisms;

(4) Toxic or deleterious chemicals;

(5) Foreign matter;

(6) Dust; or

(7) Animals.

D. Any dock or overhead door may only be open when ingredients, edible cannabis products, waste, or other items are:

(1) Received;

(2) Removed from the premises; or

(3) Moved between receiving areas.

E. Upon receipt of each delivery, a permittee shall:

- (1) Inspect for damage and potential contamination;*
 - (2) Inspect for potentially-hazardous ingredients;*
 - (3) Enter timely and accurate temperature data for potentially-hazardous ingredients;*
- and*

- (4) Confirm that:*
 - (a) Each delivery is not damaged or contaminated; or*
 - (b) Each damaged or contaminated item is recorded in the receiving log.*

F. All ingredients must be clearly labeled by the permittee with the:

- (1) Name of the ingredient;*
- (2) Batch or lot number;*
- (3) Date of receipt; and*
- (4) Expiration or use-by date.*

G. A permittee shall maintain a log for at least 2 years of the:

- (1) Date and time of each delivery of ingredients;*
- (2) Name and quantity of ingredients received;*
- (3) Batch or lot number of each ingredient received;*
- (4) Temperature data required under §E(3) of this regulation;*
- (5) Name of the product manufacturer or licensee and, if different, name of the shipping company; and*
- (6) Name of processor agent responsible for receiving the shipment.*

H. All food ingredients must be produced by a commercial manufacturer that is licensed by an approving authority.

I. Spoiled, unwholesome, vermin-infested and insect-infested ingredients are not allowed into the premises and shall be:

(1) Removed immediately from the premises and properly disposed;

(2) If it is not practicable to remove immediately, placed in a quarantine area temporarily until proper disposal; or

(3) If deemed necessary as part of an investigation by the Commission or other State, local or federal regulatory agency, placed in a quarantine area until collection.

.06 Storage of Ingredients and Edible Cannabis Products.

A. All ingredients and edible cannabis products shall be kept in a secure controlled environment that:

(1) Meets the requirements set forth in this chapter.

(2) Is a dry storage area, refrigerated storage area, or freezer storage area.

B. Storage standard operating procedures shall preserve freshness, prevent contamination, and maintain cannabinoid content of any ingredients or edible cannabis products.

C. Food ingredients may not be stored in the same areas as medical cannabis unless as outlined in standard operating procedures and approved by the Commission.

D. Storage equipment shall be positioned so that:

(1) Storage surfaces are at least 6 inches:

(a) Above the floors; and

(b) Away from the walls; and

(2) Ingredient contact surfaces are at least 18 inches above the floor.

E. Dry Storage Area.

(1) A dry storage area shall be maintained between 50° and 70° Fahrenheit; and

(2) A dry storage area shall have:

(a) Adequate ventilation to remain below 60% relative humidity; and

(b) A thermometer and hygrometer in plain sight that are calibrated based on the manufacturer's recommendations to ensure accuracy.

F. Refrigerated Storage Area.

(1) A refrigerated storage area shall:

(a) Be maintained at or below 40° Fahrenheit; and

(b) Have thermometers that are easily readable and accurate to plus or minus 2° Fahrenheit.

(2) A permittee shall:

(a) Position a temperature sensor to register the warmest air in the temperature controlled space; or

(b) Have several thermometers throughout the area to ensure accuracy, consistency, and adequate cooling.

(3) A refrigerator unit shall have doors that close tightly and seal fully.

(4) In the case of a power outage, if the refrigerator unit:

(a) Remains below 40° Fahrenheit when the power returns the refrigerator contents are considered safe; and

(b) Rises above 40° Fahrenheit for more than 2 hours then:

(i) Any ingredients or edible cannabis products shall be discarded; and

(ii) The permittee must notify the Commission within 24 hours.

G. If any ingredients or edible cannabis products that were stored in the refrigerator do not require temperature control for safety, a permittee may conduct a risk analysis to determine whether the ingredients or edible cannabis products remain safe for human consumption. The permittee shall maintain a record of any risk analysis conducted, the agent responsible for the risk analysis, and any ingredients or edible cannabis products that the permittee determines remain safe for human consumption.

H. Freezer Storage Area.

(1) A freezer storage area shall:

(a) Be maintained at or below 0° Fahrenheit; and

(b) Have thermometers that are easily readable and accurate to plus or minus 2° Fahrenheit.

(2) A permittee shall:

(a) Position a temperature sensor to register the warmest air in the temperature controlled space; or

(b) Have several thermometers throughout the area to ensure accuracy, consistency, and adequate cooling.

(3) A freezer unit shall have doors that close tightly and seal fully.

(4) In the case of a power outage, if the freezer unit:

(a) Remains at or below 0° Fahrenheit, when the power returns its contents are considered safe; and

(b) Rises above 0° Fahrenheit for more than 2 hours then:

(i) Any ingredients or edible cannabis products that were stored in the freezer shall be discarded; and

(ii) The permittee shall notify the Commission within 24 hours.

(5) If any ingredients or edible cannabis products that were stored in the freezer do not require temperature control for safety, a permittee may conduct a risk analysis to determine whether the ingredients or edible cannabis products remain safe for human consumption. The permittee shall maintain a record of any risk analysis conducted, the agent responsible for the risk analysis, and any ingredients or edible cannabis products that the permittee determines remain safe for human consumption.

I. Potentially-Hazardous Ingredients.

(1) The internal temperature of potentially-hazardous ingredient shall:

(a) Be kept at 41° Fahrenheit or less, or 135° Fahrenheit or greater; and

(b) For ingredients with a non-proteolytic Clostridium botulinum potential hazard, be

kept at 38° Fahrenheit or less during refrigerated storage; and

(2) When the internal temperature of a potentially-hazardous ingredient is kept at temperatures other than specified in §G(1):

(a) A scheduled process approved by the Commission, specifying the temperature and amount of time at that temperature, must be used; and

(b) Documentation of any corrective action taken and the agent responsible for monitoring the corrective action plan shall be kept for a minimum of 2 years and made available to the Commission upon request.

J. All ingredients and edible cannabis products shall be clearly labeled and stored in a manner that:

(1) Facilitates first-expired, first-out (FEFO) procedures; and

(2) Is approved by the Commission.

K. Each temperature controlled equipment unit shall have a temperature sensor visible from outside of the temperature controlled equipment unit.

L. For each dry storage area, refrigerator storage area, and freezer storage area, a permittee shall:

(1) Monitor the temperature 24 hours a day, 365 days a year without interruption;

(2) Document the temperature at least two times a day, 365 days a year without interruption; and

(3) If outside the specified temperature range, document the time, date, any appropriate corrective action, and the agent responsible for monitoring the corrective action plan.

G. Poisonous or Toxic Materials.

(1) A permittee shall ensure that any poisonous or toxic materials are:

(a) Kept in the original bulk container before use;

(b) Prominently and distinctively marked or labeled for easy identification;

(c) Used in accordance with manufacturer's guidelines; and

(d) Not used or stored in a way that is likely to contaminate medical cannabis, ingredients, edible cannabis products, or packaging and labeling materials.

(2) A permittee shall make a safety data sheet (SDS) that is specific to any poisonous or toxic material available to each agent in a form that the agent understands.

.07 Equipment.

A. General Requirements.

(1) The permittee shall prevent any ingredient or edible cannabis product from coming into contact with a surface or substance other than a clean and sanitary surface or substance intended for food contact or incorporation into food.

(2) Any heating and cooling equipment in close contact with ingredients or edible cannabis products shall be:

(a) Food grade;

(b) Approved for use in food processing areas; or

(c) Designed to prevent any contact with any ingredient or edible cannabis product.

(3) The permittee shall ensure that:

(a) The warewashing area includes a three-compartment sink able to hold and wash cookware and equipment in the kitchen; and

(b) Larger cookware and equipment that cannot have at least 50% of its contact surface submerged in the three-compartment sink shall comply with approved standard operating procedures for cleaning and sanitizing the cookware or equipment, and:

(i.) Agents shall be trained to clean the larger cookware and equipment according to the standard operating procedures; and

(ii.) A log shall be maintained for 2 years detailing the date, time, and agent responsible for cleaning and sanitizing the larger cookware or equipment.

(4) Equipment used to process ingredients and edible cannabis products shall be:

(a) Maintained in a sanitary and working condition;

(b) Tested and calibrated according to the equipment manufacturer's instructions to

ensure accuracy; and

(c) Positioned in a manner that does not impede proper cleaning and sanitation procedures.

(5) Equipment used to process ingredients and edible cannabis products shall meet design standards intended for food production equipment, such as those established by:

(a) National Sanitation Foundation (NSF);

(b) Bakery Industry Sanitation Standards Committee;

(c) National Automatic Merchandising Association;

(d) International Association of Milk and Food Sanitarians;

(e) American Society of Mechanical Engineers; or

(f) U. S. Department of Agriculture.

(6) A thermometer used to monitor the temperature of any ingredient, edible cannabis product, or storage area shall:

(a) Be validated at least once per month using standard operating procedures approved by the Commission; and

(b) Be calibrated based on the manufacturer's recommendations to ensure accuracy, and at a minimum:

(i) Annually; or

(ii) When validation procedures identify a thermometer is not accurate to plus or minus 2° Fahrenheit.

B. Contact Surfaces.

(1) Materials used as contact surfaces of equipment or cookware, ~~and utensils~~ shall be:

(a) Nontoxic;

(b) Inert to ingredients;

(c) Nonporous and nonabsorbent;

- (d) *Corrosion-resistant;*
- (e) *Durable;*
- (f) *If stainless steel, made of stainless steel of American Iron and Steel Institute Type 304, or equivalent; and*
- (g) *Maintained in good condition.*

(2) *Contact surfaces of equipment or cookware shall be designed, constructed, and maintained to be:*

- (a) *Smooth;*
- (b) *Easily cleanable;*
- (c) *Free of difficult to clean internal surfaces;*
- (d) *Self-emptying or self-draining if an interior surface;*
- (e) *Visible for inspection or readily disassembled for inspection;*
- (f) *If manually cleaned:*
 - (i) *Readily accessible for cleaning without tools; or*
 - (ii) *If not readily accessible, readily disassembled for cleaning with the use of simple tools kept available near the equipment; and*
- (g) *If cleaned and sanitized by pressurized cleaning-in-place system, readily accessible to the cleaning and sanitizing solutions without disassembly.*

.08 Cleaning and Sanitation Procedures.

A. General Requirements.

(1) *A permittee shall establish standard operating procedures for cleaning and sanitizing any surface, cookware, or equipment that comes into contact with ingredients or edible cannabis products that:*

- (a) *Ensures proper sanitation throughout the premises;*

(b) Is available to each agent in a form the agent understands; and

(c) Is approved by the Commission.

(2) Any surface that comes into contact with ingredients or edible cannabis products shall be cleaned and sanitized:

(a) In accordance with cleaning and sanitation procedures for food contact surfaces of cookware and equipment specified in COMAR 10.15.03;

(b) After preparing potentially-hazardous ingredients; and

(c) When there is an interruption in processing of greater than 2 hours.

(3) The permittee shall use a cleaning and sanitizing schedule and procedure demonstrated by scientific evidence to kill pathogens and be safe for use on surfaces that come into contact with ingredients and edible cannabis products.

(4) Any surface that only comes into contact with fully processed edible cannabis products shall be cleaned and sanitized:

(a) Each time more than 8 hours elapse between the start of processing and the previous cleaning and sanitizing;

(b) If processing more than one type of edible cannabis product, at a frequency sufficient to prevent cross-contamination of allergens or different dosage forms;

(c) After processing has been completed;

(d) When there is an interruption in processing of greater than 2 hours; and

(e) As often as needed during processing to prevent contamination of edible cannabis products.

B. Any surface, utensil, or equipment that does not contact ingredients or edible cannabis products shall be cleaned:

(1) According to COMAR 10.15.04; and

(2) As often as necessary to maintain sanitary conditions.

C. Vermin and insects shall be eliminated so that there is minimal potential for contamination of ingredients or edible cannabis products.

D. Pesticides may not be used to exterminate vermin unless:

(1) Approved for use in food processing areas; or

(2) The permittee:

(a) Applies the pesticides only in areas not used for storage or processing of ingredients or edible cannabis products; and

(b) Accurately enters the data into the perpetual inventory control system.

.09 Agent Sanitation.

A. The permittee shall establish standard operating procedures, that are approved by the Commission, for all aspects of agent hygiene and sanitation to ensure that each agent:

(1) Practices good personal hygiene and does not contaminate ingredients or edible cannabis products;

(2) Wears clean outerwear, and a hair and beard covering, if necessary;

(3) Wears gloves when handling any cannabis plant material or medical cannabis concentrate;

(4) If wearing gloves:

(a) Uses gloves that are intended for food contact;

(b) Washes their hands thoroughly before putting on the gloves; and

(c) Washes their hands and replaces the gloves in accordance with COMAR 10.15.03.14J and after an activity that:

(1) Is likely to soil the gloves; or

(2) Damages the gloves.

(5) If not wearing gloves, washes their hands and the exposed portions of their arms:

(a) Frequently, and after an activity that is likely to soil their hands;

- (b) Immediately upon entrance to any area containing ingredients or edible cannabis products;*
 - (c) Immediately before engaging in preparation for the production of edible cannabis products;*
 - (d) After using the lavatory;*
 - (e) After coughing, sneezing, or using a handkerchief or disposable tissue;*
 - (f) After using tobacco;*
 - (g) After eating or drinking;*
 - (h) After handling soiled linens, equipment or cookware;*
 - (i) During preparation for production of edible cannabis products, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;*
 - (j) When switching between working with ingredients or unfinished edible cannabis products and working with ~~medical cannabis~~ fully processed edible cannabis products;*
 - (k) Before donning gloves for working with edible cannabis products or ingredients;*
- and*
- (l) After engaging in any other activities that may contaminate the hands;*
- (6) If handling ingredients or edible cannabis products, maintains trim and clean fingernails and does not wear artificial fingernails; and*
- (7) Is excluded from working with ingredients or edible cannabis products, packaging materials, labelling materials, clean equipment, clean utensils, or clean linens:*
- (a) If the agent has any disease caused by:*
 - (i) Entamoeba histolytica;*
 - (ii) Vibrio cholera;*
 - (iii) Staphylococcus aureus;*

- (iv) *Escherichia coli O157:H7 or other Enterohemorrhagic or Shiga-toxin producing Escherichia coli;*
- (v) *Hepatitis A;*
- (vi) *Salmonella spp.;*
- (vii) *Shigella spp.;*
- (viii) *Norovirus;*
- (ix) *Group A beta-hemolytic Streptococcus; or*
- (x) *Salmonella Typhi, typhoid-like fever or carrier thereof; or*

(b) *If the agent has an:*

- (i) *Illness transmissible through food or edible cannabis products; or*
- (ii) *Exposed and open sore or cut.*

(c) *If the agent is experiencing:*

- (i) *Persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth;*
- (ii) *Fever;*
- (iii) *Diarrhea, unless a physician has certified the agent is noninfectious; ~~or~~*
- (iv) *Vomiting; or*
- (v) *Jaundice, unless a physician has certified the agent as noninfectious.*

B. The premises shall ensure good personal hygiene by providing:

- (1) *Lockers or similar storage facilities for the secure storage of personal items in a designated non-working area;*
- (2) *Adequate hand-washing facilities as set forth in this chapter;*
- (3) *Signage in each lavatory that instructs agents to wash their hands before returning to work;*

(4) *A water fountain or other water dispenser that provides potable water without the use of reusable cups;*

(5) *An area for agents to consume food and beverages that is not used in conjunction with the processing or storage of:*

(a) *Ingredients;*

(b) *Edible cannabis products;*

(c) *Packaging and labeling materials; or*

(d) *Cookware;*

(6) *If necessary, to ensure safety and sanitation, sanitizer foot baths, footwear covers, or hand dips.*

C. The permittee shall:

(1) *Ensure that each agent who handles ingredients or edible cannabis products successfully completes a food handler certificate course, from an entity accredited by the American National Standards Institute (ANSI) or an equivalent food safety accrediting body:*

(a) *Within 90 days of commencing employment at the premises; and*

(b) *Every three years during employment; and*

(2) *Maintain a log of agent training in ingredient and edible cannabis product handling.*

.10 Manufacture.

A. A permittee shall establish standard operating procedures to ensure the consistent and safe manufacture of edible cannabis products.

B. A standard operating procedure for the manufacture of edible cannabis products shall:

(1) *Be available to each agent in a form the agent understands;*

(2) *Accurately reflect the procedures used in the premises; and*

(3) *Be approved by the Commission.*

C. Potentially-hazardous edible cannabis products may not be manufactured unless approved by the Commission.

D. The permittee shall ensure that:

(1) Pathogenic microorganisms are excluded or eliminated from edible cannabis products before being offered for human consumption;

(2) All edible cannabis products undergo thermal processing or another process scientifically proven to kill pathogenic microorganisms that pose a threat to human health, as outlined in applicable standard operating procedures and approved by the Commission;

(3) The heating, cooling, or re-heating of ingredients or edible cannabis products use methods that prevent contamination; and

(4) All edible cannabis products are safe for human consumption.

E. The permittee shall provide a shelf-life study that meets the requirements of the Commission's current version of technical authority for medical cannabis testing, to prove the manufacturing processes prevent contamination of edible cannabis products or premature degradation of therapeutic compounds.

.11 Trade Secrets.

A. A permittee shall provide the Commission with the recipe for each edible cannabis product prior to offering the product for distribution or sale to a licensed dispensary.

B. A permittee may notify the Commission of any ingredient or recipe that the permittee considers a trade secret.

C. The Commission shall maintain the confidentiality of trade secret information in accordance with State Government Article, §10-617, and Health-General Article, §21-259, Annotated Code of Maryland.

D. If the Commission determines that the information about an ingredient or recipe is necessary to conduct a disease outbreak investigation, the Commission may disclose the trade secret to the appropriate investigators.

.12 Edible Cannabis Product Requirements.

A. General Requirements.

(1) A permittee shall obtain approval from the Commission for all edible cannabis

products prior to offering the products for distribution or sale to a licensed dispensary by submitting a request in the perpetual inventory control system.

(2) A permittee seeking approval to offer an edible cannabis product shall submit:

(a) A photograph, digital image, or digital rendering of the product, labeling, and packaging;

(b) The varying levels of potency and dosing of the edible cannabis product;

(c) The recipe, including the production process, for manufacturing the edible cannabis product; and

(d) Any scientific studies or laboratory testing results supporting the stability and approximate expiration date of the edible cannabis product.

(3) The Commission shall review and approve each edible cannabis product before the product may be commercially manufactured or sold by a permittee to ensure the:

(a) Product complies with the requirements of this chapter; and

(b) Safety of minors.

B. Dosage Requirements.

(1) Unless expressly authorized by the Commission, an edible cannabis product may not contain more than:

(a) 10 milligrams of THC per serving; and

(b) 100 milligrams of THC per package.

(2) A permittee is encouraged to manufacture varying levels of potency for each edible cannabis product the permittee distributes, including products containing:

(a) 2.5 milligrams of THC per serving; and

(b) 5 milligrams of THC per serving.

(3) Each single serving contained in a package of a multiple-serving solid edible cannabis product shall be physically separated in a way that enables a patient to determine how much of the edible cannabis product constitutes a single serving.

(4) A package containing more than one serving of non-solid edible cannabis product shall:

(a) Have a resealing cap or closure; and

(b) Include within the package a measuring device that is appropriate for the product form, such as a measuring cap or dropper for liquids or a measuring spoon for powders. ~~Has marks on the bottle or package do not qualify as a measuring device.~~

(5) A package containing more than one serving of a liquid edible cannabis product may have a non-opaque strip or measuring marks on the bottle or package, but the strip or marks do not suffice as a measuring device.

(6) A permittee seeking to manufacture an edible cannabis product containing more than 10 milligrams of THC per serving or 100 milligrams of THC per package shall submit a request, in a form prescribed by the Commission, that provides scientific or medical evidence or research that supports the use of higher doses of THC to treat a qualifying medical disease or condition.

(7) The Commission may deny a request under §B(6) of this regulation if:

(a) The request is facially insubstantial; or

(b) The Commission determines that:

(i) The scientific or medical evidence or research is inadequate; or

(ii) The potential risks to patients and to the safety of minors outweighs the potential benefits.

(7) An edible cannabis product consisting of multiple servings shall be homogenized so that each serving contains the same concentration of THC.

D. Appearance of Edible Cannabis Products.

(1) A solid edible cannabis product may only be manufactured or distributed in geometric shapes.

(2) A permittee may not manufacture an edible cannabis product that due to its shape, design, or flavor is likely to appeal to minors.

(3) The manufacture or sale of edibles in the following shapes is prohibited:

(a) Human, animal, or fruit;

(b) A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings; and

(c) A commercially available food or beverage product that targets, or is primarily marketed to, minors.

E. Prohibited Products.

(1) Edible cannabis products may not contain:

(a) Meat;

(b) Seafood;

(c) Unpasteurized eggs; or

(d) Unpasteurized dairy of any type; and

(2) The following types of products may not be sold:

(a) Alcoholic beverages, as defined in Alcoholic Beverage Article, §1-101, Annotated Code of Maryland; and

(b) Any product containing any non-cannabis additive that would increase potency or toxicity, or that would create an unsafe combination with other psychoactive substances. Prohibited additives include, nicotine and caffeine. This prohibition shall not apply to products containing naturally-occurring caffeine, such as coffee, tea, or chocolate.

.13. Edible Cannabis Packaging Requirements.

A. All edible cannabis product packaging shall comply with the requirements established in COMAR 10.62.24 and COMAR 10.62.29.

B. Any container or packaging containing edible cannabis products shall protect the contents from contamination.

C. Edible cannabis product packaging shall:

(1) Be designed and installed to maintain product safety and integrity;

(2) Be made from materials that are food safe, are appropriate for the intended use, and that cannot migrate to or be absorbed by the edible cannabis product;

(3) Comply with the food additive requirements established in 21 CFR §§ 174 – 178;

(4) Be tamper-evident;

(5) Comply with the child-resistant packaging requirements established in 16 CFR §1700;

(6) If intended for multiple openings, be capable of being resealed and sustain being child-resistant after the container or package has been opened;

(7) Be stored so that the edible cannabis product is protected from contamination; and

(8) Not be reused.

D. Prior to use, a permittee shall evaluate the edible cannabis product packaging for:

(1) Permeability to:

(a) Water;

(b) Water vapor;

(c) Oxygen; and

(d) Other gases; and

(2) Tolerance to:

(a) Heat;

(b) Cold;

(c) Chemicals used in processing;

(d) Strength; and

(e) Elasticity.

E. Packaging of an edible cannabis product that contains multiple servings shall include a statement on the exterior of the package indicating the packaging contains multiple servings and the number of servings contained within.

.14 Edible Cannabis Product Labeling Requirements.

A. An edible cannabis product label shall comply with the requirements established in COMAR 10.62.24 and 10.62.29.

B. An edible cannabis product label shall include:

(1) A list of:

(a) Ingredients and sub-ingredients in descending order of prominence; and

(b) Any natural or synthetic preservative added; and

(2) A statement of any common food allergens, as indicated in the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. §301 et seq., that an edible cannabis product may contain, including:

(a) Eggs;

(b) Soybeans;

(c) Milk;

(d) Wheat;

(e) Peanuts;

(f) Tree nuts;

(g) Fish; or

(h) Crustacean shellfish;

(3) The processing date;

(4) The expiration date, which shall be:

(a) Supported by scientific evidence, such as formal stability or challenge studies conducted on similar conventional food products;

(b) Supported by stability studies conducted following guidelines indicated in the Commission's current version of technical authority; and

(c) Calculated based on a shelf-life approved by the Commission for the specific edible cannabis product.

(5) A warning that states: “CAUTION: When consumed by mouth the effects of this product can be immediate or delayed by 2 or more hours.”.

C. Edible cannabis product labels shall be able to remain conspicuous, durable, and legible for the shelf-life of the edible cannabis product.

.15 Limited Testing for Research and Development Purposes.

A. A licensed processor may process edible cannabis products for research and development purposes to facilitate safe edible cannabis product development and innovation.

B. The research and development of the edible cannabis products under this regulation may not include testing of any type on human or animal subjects.

C. Edible Cannabis Product Development.

A licensed processor who processes edible cannabis products for research and development shall:

(1) Track the medical cannabis used for research and development in the perpetual inventory control system;

(2) Quarantine each batch or lot in a quarantine area and label each batch or lot with a distinctive label;

(3) Process the medical cannabis for research and development during a time that does not overlap with the processing of any medical cannabis that will be intended for human consumption;

(4) Establish standard operating procedures for cleaning and sanitation that :

(a) Include protocols for adequately cleaning processing areas, cookware and equipment in between processing edible cannabis products for research and development purposes and processing products intended for human consumption; and

(b) Are approved by the Commission.

D. Research and Development Testing.

(1) A licensed processor may conduct the research and development testing on the processor’s premises or through an independent testing laboratory.

(2) *If an independent testing laboratory conducts the research and development testing on the edible cannabis product, the laboratory shall clearly mark any certificate of analysis or reporting of test results with “R&D TESTING ONLY” on the header and footer of the report in 20-point white font and a red background.*

E. Any edible cannabis product transferred from the licensed premises for research and development testing shall:

(1) *Be packaged in accordance with COMAR 10.62.37.13C; and*

(2) *Be labelled with the statements:*

(a) *“CAUTION: NOT FOR HUMAN OR ANIMAL CONSUMPTION.”;*

and

(3) *“This product has not been approved by the Maryland Medical Cannabis Commission and is intended for research and development purposes only.”*

(4) *Identify the name and telephone number of the licensed processor who manufactured the product; and*

(5) *Include a unique identifying number.*

F. A batch or lot of medical cannabis originally used or processed for research and development purposes:

(1) *May not be used in the processing of medical cannabis sold to a licensed dispensary; and*

(2) *Shall be destroyed and logged as green waste.*

G. A licensed processor shall maintain a record of all research and development tests for at least 2 years and provide copies of the test results to the Commission, upon request.

.16 Transport of Edible Cannabis Products.

A. The transport of edible cannabis products shall comply with the medical cannabis shipment requirements established in COMAR 10.62.18.

B. If transporting edible cannabis products that require temperature control for safety and stability, a permittee shall ensure the vehicle or transportation equipment:

(1) *Provides adequate temperature control to prevent the edible cannabis products from becoming unsafe during transport; and*

(2) *Complies with the requirements established in 21 CFR §1.908(c).*

C. A permittee shall maintain a detailed log of the temperature of the edible cannabis products at the time of departure for at least 2 years.

D. The receiving licensee shall maintain a detailed log of the temperature of the edible cannabis products at the time of arrival at the licensed dispensary for at least 2 years.

E. If any edible cannabis products are declined upon arrival to the licensed dispensary due to contamination, damage, or an unsafe temperature the permittee shall within 24 hours:

(1) Document the declination and the reason for the declination in the perpetual inventory control system;

(2) Dispose of the rejected material in accordance with the permittee's approved green waste disposal plan.

.17 Dispensary Responsibilities.

A. A licensed dispensary may not store or distribute edible cannabis products unless the licensed dispensary:

(1) Submits the licensee's standard operating procedures for receipt, storage, and distribution of all edible cannabis products to the Commission; and

(2) Passes a Commission inspection and the operations conform to the standard operating procedures for the receipt, storage, and distribution of all edible cannabis products.

B. Each licensed dispensary shall offer for sale containers for the storage of medical cannabis that lock and are designed to prevent children from unlocking and opening the container.

.18 Laboratory Testing.

A. Each lot of edible cannabis products shall be tested by a registered independent testing laboratory for:

(1) Cannabinoid content:

(a) THC, which shall be +/-10% of any amount indicated on the edible cannabis product label;

(b) Any other cannabinoids indicated in the Commission's current version of technical authority; and

(c) Any cannabinoid identified on the package or label of the edible cannabis product;

(2) Microbiological impurities:

(a) Shiga-toxin producing *Escherichia coli* <1 CFU/g (undetectable);

(b) *Salmonella* spp. <1 CFU/g (undetectable);

(c) Total of aflatoxin B1, B2, G1, and G2 <20 µg/kg of substance; and

(d) Ochratoxin A <20 µg/kg of substance;

(3) Water activity (*aw*), which shall be 0.85 or less unless approved by the Commission;

(4) A visual inspection of the edible cannabis product to identify:

(a) The presence of any foreign matter;

(b) Any abnormal odors or colors; and

(c) Any inconsistencies between servings of an edible cannabis product; and

(5) Any other tests required by the Commission's current version of technical authority for medical cannabis testing.

A. A permittee shall ensure homogeneity and establish the validity of the production process for all edible cannabis products by implementing written standard operating procedures that comply with the Commission's current version of technical authority for medical cannabis testing.

B. Random sampling and stability studies shall comply with the requirements established in the Commission's current version of technical authority for medical cannabis testing.

.19 Exceptions.

A licensee may not use an alternative method of receiving, storing, sanitizing, delivering, processing, monitoring, or verifying edible cannabis products or edible cannabis product equipment, cookware, or procedures unless authorized by the Commission.

.20 Compliance with State and Federal Food Safety Requirements.

Although edible cannabis products are not defined as or regulated by the same approving authority as food, in addition to the other requirements set forth in this chapter, a permittee shall comply with all applicable food safety regulations including:

- A. *21 CFR, as amended;*
- B. *21 U.S.C. §343, as amended;*
- C. *21 U.S.C. §§451—471, as amended; and*
- D. *21 U.S.C. §§601—695, as amended.*

.21 Medical Cannabis Products and Components not Subject to this Chapter.

A. *Regulations .01 – .19 of this chapter do not apply to the following:*

- (1) Dried leaves and flowers of the cannabis plant;*
- (2) Medical cannabis concentrates; and*
- (3) Medical cannabis-infused products as defined in 10.62.23.01B(3)(c).*

B. *A licensed processor may submit a request to the Commission to exempt a medical cannabis product intended for human consumption by oral ingestion, in whole or part, from Regulations .01 – .19 of this chapter if the dosage form is recognized by the United States Pharmacopeia, the National Formulary, or the Food and Drug Administration.*

C. *The Commission may approve a request to exempt a dosage form from Regulations .01 – .19 under the following conditions if the licensed processor submits:*

- (1) A completed application in a form prescribed by the Commission;*
- (2) Standard operating procedures for all aspects of the receipt, processing, storage, packaging, labeling, handling, tracking, and shipping of products in the dosage form;*
- (4) The dosage form is recognized by the United States Pharmacopeia, the National Formulary, or the Food and Drug Administration; and*
- (4) The licensed processor is certified by an accredited third-party certification body in an alternative pharmaceutical or dietary supplement certification approved by the Commission.*